REMARKS

I. Preliminary Remarks

The present invention relates to a delivery system for pharmacologically active molecules through the use of optionally substituted tripeptides. The tripeptides of the present invention are able to rapidly bind to blood cells such that those cells function to deliver drugs to sites in the body where a substantial proteolytic activity takes place. Such sites include those with arthritis, tumors, invasive parasitic diseases and the like and proteolytic enzymes present at those sites cleave the tripeptides to liberate the pharmacologically active molecules at those desired locations.

Claim 1 has been amended to incorporate various of the limitations of claims 3, 4 and 5 now canceled. In particular, claim 1 has been amended to recite a select group of tripeptides each of which comprises a not terminal Phe. In addition, the amended language makes clear that the drug is connected to the not terminal proteolytic enzyme cleavable amino acid moiety (i.e., the not terminal Phe). Claim 7 has been amended to clarify that it is not a tripeptide connected to a drug as claimed in claim 1 but a reactive precursor of such a peptide and reentry into prosecution of that claim and each of withdrawn claims 2, 6 and 18 is solicited in light of the amendments to claims 1 and 7.

II. Outstanding Rejections

Claims 1 and 4 stand as objected to for various informalities.

Claim 1 stands rejected under 35 U.S.C. §112 (second paragraph) as being indefinite for reciting "pharmacologically active site."

Claim 5 is also rejected under 35 U.S.C. §112 (second paragraph) as being indefinite for reciting tetrapeptides and for double reciting "pro-phe-phe."

Claims 1, 3-5, 8, 11, 16 and 20 stand rejected under 35 U.S.C. §112 (first paragraph) as failing to comply with the written description requirement

Claims 1, 5, 8 and 16 stand rejected under 35 U.S.C. §102(e) as being anticipated by Pei et al., US 2004000956 as disclosing one of the tripeptides claimed in claim 5

Claims 1, 3-4, 11 and 16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bebbington WO 200200263.

III. Patentability Arguments

A. The Objection to Claims 1 and 4 Should Be Withdrawn in light of the amendment of the claims.

The objections to claims 1 and 4 should be withdrawn in light of the amendment of claim 1 in accordance with the suggestion of the Examiner and the cancellation of claim 4.

B. The Rejection of Claims 1 and 5 Under 35 U.S.C. §112 (second paragraph) Should Be Withdrawn in light of the amendment of the claims.

The rejection of claims 1 and 5 for indefiniteness should be withdrawn in light of the amendment of the claims to delete recitation of a pharmacologically active site and of tetrapeptides.

C. The Rejection of Claims 1 3-5, 8, 11, 16 and 20 under 35 U.S.C. §112 (first paragraph) for lack of Written Descriptive Support Should Be Withdrawn in light of the amendment of the claims.

The rejection under 35 U.S.C. §112 (first paragraph) for lack of written descriptive support should be withdrawn in light of the amendment of claim 1 to restrict it to tripeptides explicitly mentioned in claim 5 (now canceled). These tripeptides can then be coupled to any drug that as such is suitable for the treatment of arthritis, invasive parasitic diseases, Paludism (Malaria) AIDS and tumors, especially cancer to act as a transport and delivery system. (See the specification at page 2, lines 25-27) Suitable drugs are well known to those of ordinary skill.

D. The Rejections of Claims 1, 3-4, 11 and 16 Under 35 USC §102(b) in view of Bebbington (W0200200263) Should Be Withdrawn.

The rejection of claims 1, 3-4, 11, and 16 under 35 U.S.C. 102(b) as being anticipated by Bebbington should be withdrawn because Bebbington teaches coupling of a pro-drug through the O-terminal group (not a "not terminal group") and does not disclose the tripeptides of amended claim 1. In addition, Bebbington teaches the stabilization of the N-terminus by e.g. succinate which functions to prevent cleavage by proteases! (see page 13, lines 24-32). For these reasons the rejection under 35 U.S.C. §102 over Bebbington should be withdrawn and no new rejection over 35 U.S.C. §103 need be made.

E. The Rejections of Claims 1, 5, 8 and 16 Under 35 USC §102(e) in view of Pei et al. (US20040009956) Should Be Withdrawn.

The rejection of claims 1, 5, 8 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Pei et al. should be withdrawn because Pei discloses coupling of a drug to the terminal residue of a tripeptide and because it does not disclose Phe as the not terminal cleavable amino acid moiety. (Note that each of the substituted or unsubstituted tripeptides of amended claim 1 comprises a not terminal Phe.)

In addition, Pei is directed to the treatment of diabetes and obesity which are not related to high protease activity. As such it neither discloses nor suggests liberation of a pharmacologically active moiety at protease rich body sites such as those recited in the amended claim 1. For these reasons the rejection under 35 U.S.C. §102 over Pei should be withdrawn and no new rejection over 35 U.S.C. §103 need be made.

CONCLUSION

For the foregoing reasons, it is submitted that each of claims 1, 2, 6-8, 11, 16, 18 and 20 should now be allowed. Should the Examiner wish to discuss any issues of form or substance, he is invited to contacted the undersigned attorney at the number below.

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Respectfully submitted,

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